

REMARKS

Applicants have amended claims 1, 8, 10, 12, 16, and 17, and cancelled claims 6, 7, 11, and 15. In particular, to more particularly point out the subject matter they regard as their invention, Applicants have limited claim 1 to a polymeric support in the form of a strip, and have limited claims 10 and 17 to a delivery system positioned between an inner core and an outer layer. Support for the amendments can be found in the Specification at page 6, lines 16-23; and page 9, lines 15-17, respectively. Applicants have also corrected a misspelling in claim 10. Finally, cancellation of claims 6, 7, 11, and 15 has necessitated change of the dependencies of claims 8, 12, and 16.

Claims 1-5, 8-10, 12-14, and 16-19 are now pending. Reconsideration of the application, as amended, is requested in view of the remarks below.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-19 under 35 U.S.C. § 102(b) as being anticipated by Zaffaroni, U.S. Patent 3,993,073 ("Zaffaroni"). See the Office Action, page 2, lines 9-10. Applicants disagree.

Amended claim 1 is drawn to a transvaginal drug delivery system that contains (1) a polymeric support in the form of a strip, and (2) a drug deposited on the polymeric support.

Zaffaroni teaches a drug delivery system having two components, i.e., a wall and a reservoir. See column 8, lines 60-67. The wall, a continuous surface enclosing the reservoir, is made of a drug-permeable material that controls the rate of drug release. See column 3, lines 32-40.

The system disclosed in Zaffaroni differs substantially from that of claim 1. In the Zaffaroni system, the wall, corresponding to the support in the system of claim 1, is not in the form of a strip as required by claim 1. Rather, it is a continuous surface instead of a strip. As the system of claim 1 is different from the Zaffaroni system, claim 1 is novel over Zaffaroni. So are claims 2-5, 8-10, 12-14, and 16-19, each of which includes all of the limitations of claim 1.

Applicants would like to point out that claims 10 and 17 are also novel over Zaffaroni on an additional and independent ground. Claim 10, as amended, covers a tampon which includes three components: (i) an inner core made of an absorbent material, (ii) an outer layer made of a permeable material, and (iii) the system of claim 1 positioned between the inner core and the

outer layer. Claim 17 covers a method of transvaginal drug delivery via inserting into a vagina a tampon that contains components (i), (ii), and (iii). Zaffaroni does not mention a tampon having components (i), (ii), and (iii). Thus, claims 10 and 17 are not anticipated by Zaffaroni. Neither are claims 12-14 and 16 (which depend from claim 10) and claims 18-19 (which depend from claim 17).

References cited but not relied on by the Examiner

Myhling, U.S. Patent 6,328,991 ("Myhling"), Theeuwes et al., U.S. Patent 4,077,407 ("Theeuwes '407"), and Theeuwes, U.S. Patent 4,256,108 ("Theeuwes '108") were cited but not relied on by the Examiner. See the Office Action, page 2, lines 12-15. For the sake of a complete record, Applicants would like to discuss these prior art references.

Myhling discloses a system containing a removable, pre-moistened vaginal sponge impregnated with a solution that contains a carrier and a drug. The system contains "an amount of [a drug-containing] solution that is tightly held by the sponge, i.e., blocked therein." See column 6, lines 11-18. In the Myhling system, the drug is blocked in a sponge instead of deposited on a polymeric support as required by claim 1. Thus, the Myhling system is different from that of claim 1.

Theeuwes '407 discloses an osmotic system for delivering an active agent. The system has (a) a spherical wall surrounding a compartment, and (b) a passageway through the wall for releasing the agent. See the abstract and figure 1B. This system disclosed in this reference differs considerably from that of claim 1. In this system, the wall, corresponding to the support of claim 1, is not in the form of a strip as required by claim 1. Rather, it is spherical instead of strip-like. Thus, the Theeuwes '407 system is different from that of claim 1.

Theeuwes '108 discloses a system containing a drug delivery module which includes (a) a rate-controlling laminated wall surrounding a reservoir, and (b) a portal for delivering drug from the system. The laminated wall forms a continuous surface and contains a semi-permeable lamina. See the abstract and Figure 11. In the Theeuwes '108 system, the wall, corresponding to the support of claim 1, is in a continuous surface, rather than a strip as required by claim 1. In other words, the Theeuwes '108 system is different from that of claim 1.

Based on the remarks set forth above, Applicants submit that these three references do not anticipate claim 1, as well as the other claims which include all the limitations of claim 1.

Applicant : Simon Benita, et al
Serial No. : 10/082,819
Filed : February 25, 2002
Page : 8 of 8

Attorney Docket No.: 13962-002001 / 137745.6 JP/dab

CONCLUSION

Applicants believe that all claims, as amended, cover allowable subject matter, and should be allowed. Early allowance by the Examiner is respectfully solicited.

Enclosed is a Petition for One Month Extension of Time, with the required fee of \$60. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket 13962-002001.

Respectfully submitted,

Date: 1-19-05

Y. Rocky Tsao
Y. Rocky Tsao
Reg. No. 34,053

PTO Customer No. 26161
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906
20995456.doc